

Economic Impact Statement

LSA Document #07-590

IC 4-22-2.1-5 Statement Concerning Rules Affecting Small Businesses

This proposed rule adds [856 IAC 5](#) to establish standards applicable to all pharmacies and facilities that utilize and rely on automation technology to store, package, dispense, and distribute prescriptions or medication orders. The proposed rule defines "automated medication system".

"Automated medication system" means any technology assisted operation approved by the board which relies on bar code or other automated technology to dispense and distribute medications and which records all transactions related to its operation. This term does not include automatic counting devices or unit-based dispensing cabinets utilized by a pharmacy or facility to automatically count medication for dispensing.

Many companies produce automated medication systems. These systems are utilized by pharmacy benefit management companies, pharmacies, hospitals, ambulatory surgery centers, and nursing care facilities. These systems enable providers to produce medication doses for patients, track supply and drug utilization, and increase security. The systems automatically generate reports covering inventory, drug dispensing, discrepancies, billing, and medication delivery.

There are multiple types of machines that fall under the category of automated medication systems.

Examples include:

- Fully automated ATM-style dispensers of prescription medications. These systems dispense medications directly to consumers at the point-of-care, such as the waiting rooms of clinics and hospital emergency departments.
- Computer-automated drug storage and dispensing systems used in hospitals, nursing homes, and ambulatory surgery centers to store and dispense drugs.
- Centralized computer systems, typically housed in a hospital pharmacy, designed to track inventory, drug dispensing, discrepancies, billing, and medication delivery.
- Pharmacy benefit managers that utilize automated medication system to provide prescriptions for their members through mail order and the Internet.

Impact on Small Businesses**1. Estimate of the number of small businesses, classified by industry sector, that will be subject to the proposed rule:**

NAICS CODE 446110	Pharmacies	400*
NAICS CODE 621	Ambulatory Health Care	160
NAICS CODE 622	Hospitals	125
NAICS CODE 623	Nursing and Residential Care Facilities	
	Comprehensive Care Facilities	518
	Residential Care Facilities	88

[IC 4-22-2.1-4](#) provides that "small business" means any person, firm, corporation, limited liability company, partnership, or association that:

- (1) is actively engaged in business in Indiana and maintains its principal place of business in Indiana;
- (2) is independently owned and operated;
- (3) employs one hundred (100) or fewer full-time employees; and
- (4) has gross annual receipts of five million dollars (\$5,000,000) or less.

Of the approximately 1,400 retail pharmacies in Indiana, staff of the Indiana Board of Pharmacy estimates that 1,000 are chain drug stores that do not meet the definition of a small business.

2. Estimate of the average annual reporting, record keeping, and other administrative costs that small business will incur to comply with the proposed rule.

The proposed rule does not mandate the use of automated medication systems by any entity. If an entity elects to utilize an automated medication system, the entity will be required to comply with the rule. The rule will not affect those pharmacies utilizing automatic counting machines and unit dose dispensing equipment such as are typically found in small retail pharmacies.

The cost of automated dispensing derives principally from the capital investment of renting or purchasing equipment for dispensing, labeling, and tracking. Expenses can be offset by reduced numbers of personnel needed to perform these functions, decreased drug waste, reduction in medication dispensing time, and improved billing efficiency.

Since the rule does not mandate the use of automated medication systems by small businesses, small businesses will incur reporting, record keeping, and other costs to associated with automated medication systems

only if they elect to rent or purchase the equipment.

It should be noted that all pharmacies are required to engage in record keeping related to drug delivery by both state and federal law.

The automated medication systems track the information required by the rule. The rule essentially provides baseline requirements to guide affected pharmacies and facilities utilizing automated technology so that they comply with already existing statutorily required record keeping.

3. Estimate of the total annual economic impact that compliance with the proposed rule will have on all small businesses subject to the rule.

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4. Statement justifying any requirement or cost that is imposed on small businesses by the rule; or any other state or federal law.

These systems enable providers to produce medication doses for patients, track supply and drug utilization, and increase security.

5. Regulatory flexibility analysis.

Consideration of alternative methods of achieving the purpose of the proposed rule

The alternative is to not require records to be maintained but, that was rejected as being contrary to the board's duty to protect patient safety. As noted previously, pharmacies maintain records under existing state and federal laws. This rule defines the protocols for collecting said data through automated systems.

Conclusion

Public safety is the primary Board responsibility. The use of automated medication systems continues to increase because of the ability to track by automation what was formerly done manually. These systems generate reports which include inventory, drug dispensing, discrepancies, patient information, billing, and medication delivery. By placing into rule the requirements for utilizing and maintaining automated systems, affected pharmacies and facilities will have the information they need to remain compliant with state pharmacy and legend drug laws.

Supporting Data, Studies, or Analyses

Cost-benefit analysis of an automated medication system, Nursing Economics, July-August, 1996 by Lowell C. Wise, Janet Bostrom, Janice A. Crosier, Sarah White, Richard Caldwell

Making Health Care Safer: A Critical Analysis of Patient Safety Practices. Evidence Report/Technology Assessment: Number 43. AHRQ Publication No. 01-E058, July 2001. Agency for Healthcare Research and Quality, Rockville, MD.

<http://www.ahrq.gov/clinic/ptsafety/>

<http://instymeds.com/>

<http://www.cardinal.com/us/en/providers/products/pyxis/>

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